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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,144	02/13/2006	**Michel Afargan**	27242U	7760

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EXAMINER	
REMALY, MARK DONALD	
ART UNIT	PAPER NUMBER
3737	
MAIL DATE	DELIVERY MODE
07/12/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,144	AFARGAN ET AL.	
	Examiner	Art Unit	
	Mark Remaly	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *53-94* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *53-94* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 70, 76, 77 and 86-90 objected to because of the following informalities: Claim 70 should properly definite the acronym GRDA. The claims 76, 77 and 86-90 fail to set forth an active step in the method. Appropriate correction is required.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 92 and 93 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 58-61, 66, 68, 85, 92 and 93 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 58 and 59 include improper Markush type claim language that renders the claim indefinite.

7. Claim 61 recites the limitation "said contrasting agent" in line 2. There is insufficient antecedent basis for this limitation in the claim.

8. Claims 66 and 68 are indefinite in that the language appears to be more directed to a method of making the device.

9. Claim 85 recites the limitation "said time window" in line 3. There is insufficient antecedent basis for this limitation in the claim.

10. Claims 92 and 93 provide for the use of a generally planar single or multi-layered device, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

11. Claims 70-91 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: Imaging the GI tract.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 53-60, 62-67, 69-77, 79-85 and 92 are rejected under 35 U.S.C. 102(b) as being anticipated by Caldwell et al. (US Pat. No. 4,767,627).

Caldwell et al. ('627) teach a gastric retention device which resides in the confines of the stomach for the purpose of providing a platform for controlled release of biologically active agents. A planar disc-shaped or multi-lobed flat or planar device may be used which is large enough and rigid enough such that said device will not pass out of the stomach but will allow passage of food around said device. Preferred configurations are illustrated in FIGS. 1-6 (see column 4, lines 8-17).

The desired expanded configuration of the device is too large to be swallowed and thus must be compressed and contained in a conventional capsule or like container for swallowing. The capsule is designed to dissolve after oral ingestion within the confines of the stomach. The compressed device within the capsule container reaches the stomach, upon dissolution and/or disintegration of the retaining capsule or like container, said device will expand or unfold in such a manner that results in its original shape which is too large to pass from the stomach into the intestine unless enough force is applied to recompress the device. This "expanded" form of the device will remain in the stomach for a pre-determined period of time depending on the desired time profile of release of the biologically active agent, which is a part of the device or contained within a controlled release module that is attached to the retention device. The "pre-determined time" is preferably within the range of 1 hour to 1 year (see column 4, lines 27-61).

In example 1 of Caldwell et al., studies were performed with Beagle dogs in order to ascertain gastric retention time of the drug delivery device described herein. The parameters investigated were size, shape and erodibility. These devices were administered in gelatin capsules and their position in the gastrointestinal tract determined using x-ray techniques. Barium sulfate, a well-known contrast agent, was attached to the device and released into the digestive tract at a calculated retention rate. The data indicate that the retention of these devices in the stomach is a function of their diameter and that retention for a period of 24 hours is possible using devices which can be folded into gelatin capsules suitable for swallowing (see column 7, lines 32-55). X-ray is an imaging method that utilizes barium sulfate, a well-known diagnostic utility, in example 1.

The drug may be dispersed as a solution or suspension within an erodible polymer matrix such that as the matrix erodes within the confines of the gastric pouch, the drug is released at a predetermined rate. Similarly, the drug may be dissolved or dispersed within a non-erodible matrix material comprising part of the retention device. As this matrix comes in contact with gastric fluid, the drug diffuses out of the non-erodible matrix at a predetermined rate (see column 6, lines 27-31) .

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Caldwell et al. (US Pat. No. 4,767,627) in view of Friedman et al. (US Pat. No. 6,685,962 B2).

Caldwell et al. ('627) teach a gastric retention device as discussed above but do not explicitly teach a multiple layer matrix. However, Friedman et al. ('962) from the same field of endeavor do teach a pharmaceutical gastroretentive drug delivery system for the controlled release of an active agent in the gastrointestinal tract, which system comprises: a) a single- or multi-layered matrix having a two- or three-dimensional geometric configuration comprising a polymer that does not retain in the stomach more than a conventional dosage form, said polymer selected from: (1) a degradable polymer selected from: (i) a hydrophilic polymer which is not instantly soluble in gastric fluids; (ii) an enteric polymer substantially insoluble at pH less than 5.5; (iii) a hydrophobic polymer; and (iv) any mixture of at least two polymers as defined in (i), (ii) or (iii); (2) a non-degradable; and (3) a mixture of at least one polymer as defined in (1) with at least one polymer as defined in (2); b) a continuous or non-continuous membrane, that does

not retain in the stomach more than a conventional dosage form, affixed or attached to said matrix, said membrane comprising at least one polymer having a substantial mechanical strength; and c) a drug, which may be in a particulate form or optionally contained within a drug-containing means; said drug or drug contained within said drug-containing means being embedded in a layer of said matrix, or being entrapped between at least two layers of said matrix, or being attached to said delivery system, wherein said matrix when affixed or attached to said membrane prevents evacuation from the stomach of said delivery system for a period of time of from about 3 to about 24 hours (see column 3, lines 4-39). It would be obvious to one or ordinary skill in the art to combine the invention of Caldwell et al. ('627) with the multiple layer matrix of Friedman et al. ('962) for the precise control of drug delivery.

17. Claims 68 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caldwell et al. (US Pat. No. 4,767,627) in view of Curatolo et al. (US Pat. No. 5,443,843).

Caldwell et al. ('627) teach a gastric retention device as discussed above but do not explicitly teach a device folded in a fan-like configuration. However, Curatolo et al. ('843) from the same field of endeavor do teach a pharmaceutical gastroretentive drug delivery system for the controlled release of an active agent in the gastrointestinal tract, which system comprises a device folded in a fan-like configuration. It would be obvious to one or ordinary skill in the art to combine the invention of Caldwell et al. ('627) with the a device folded in a fan-like configuration of Curatolo et al. for enhanced stomach retension.

18. Claims 86-91, 93 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caldwell et al. (US Pat. No. 4,767,627) in view of Unger (US Pat. No. 6,024,939).

Caldwell et al. ('627) teach a gastric retention device as discussed above but do not explicitly teach imaging for the purpose of pathological diagnostics. However, Unger ('939) from the same field of endeavor do teach imaging techniques that have been used to diagnose disease in humans. To improve the diagnostic utility of this imaging technique, contrast agents are employed in an attempt to increase the differences in density between various structures, such as between the gastrointestinal tract and its surrounding tissues. Barium and iodinated contrast material, for example, are used extensively for X-ray gastrointestinal studies to visualize the esophagus, stomach, intestines and rectum. Likewise, these contrast agents are used for X-ray computed tomographic studies to improve visualization of the gastrointestinal tract and to provide, for example, contrast between the tract and the structures adjacent to it, such as the vessels or the lymph nodes. Such gastrointestinal contrast agents permit one to increase the density inside the esophagus, stomach, intestines and rectum, and allow differentiation of the gastrointestinal system from surrounding structures (see column 1, lines 25-44).

The invention of Unger is used in diagnosing the presence of diseased tissue in a patient. The imaging process of the present invention may be carried out by administering a contrast medium of the invention to a patient, and then scanning the patient using ultrasound imaging to obtain visible images of an internal region of a

patient and/or of any diseased tissue in that region. By region of a patient, it is meant the whole patient, or a particular area or portion of the patient. The contrast medium is particularly useful in providing images of the gastrointestinal region, but can also be employed more broadly such as in imaging any body cavities, or in other ways as will be readily apparent to those skilled in the art, such as in imaging the vasculature, liver, and spleen, and for use in tissue characterization. The phrase gastrointestinal region or gastrointestinal tract, as used herein, includes the region of a patient defined by the esophagus, stomach, small and large intestines and rectum. Any of the various types of ultrasound imaging devices can be employed in the practice of the invention, the particular type or model of the device not being critical to the method of the invention (See column 7, line 62-column 8, line 21).

It would be obvious to one or ordinary skill in the art to combine the invention of Caldwell et al. ('627) with the pathological diagnostics of Unger ('939) for the purpose of identifying any number of gastrointestinal diseases such as polyps, cancer, bleeding, gastritis, ulcers or any other well-known condition that can be diagnosed through the use of imaging.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Remaly whose telephone number is (571) 270-1491. The examiner can normally be reached on Monday - Friday 7:30am-5:00pm, alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Remaly/
Examiner, Art Unit 3737

/Ruth S. Smith/
Primary Examiner, Art Unit 3737